

Remarks

Previously filed Terminal Disclaimer

The action states, on page 3, that the terminal disclaimer, to pending application 10/012,804, filed October 24, 2005, has not been considered because the fee was not authorized. Applicants' records indicate that small entity fees for two terminal disclaimers, \$130, was paid on November 22, 2005.

Double Patenting:

Claims 11 and 13-17 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 and 7 of copending Application 10/186,757. With this Response, Applicants have filed a terminal disclaimer to overcome the rejection.

Rejection of the Claims under 35 USC § 112

Claim 18 has been rejected under 35 U.S.C. 112, second paragraph, because the term "solution" does not have proper antecedent basis. Applicants have amended the claim to obviate the rejection.

Rejection of the claims under 35 USC § 102

Claims 11, 13, 14, 15, and 17 have been rejected under 35 U.S. C. 102(b) as being anticipated by Sioud et al. (Nature Biotech. 1998). Applicants respectfully disagree. Claim 1 clearly states that the complex is inserted into a vessel. In contrast, Sioud teaches injection into the center of a tumor.

Claims 11, 13, 14, and 17 have been rejected under 35 U.S. C. 102(b) as being anticipated by Czubayko et al. (PNAS 1996). Applicants respectfully disagree. Claim 1 clearly states that the complex is inserted into a vessel in a mammal. In contrast, Czubayko teaches transfection of the ribozyme into cells in vitro and then insertion of the cells into mice in vivo.

Rejection of the claims under 35 USC § 103

Claims 11 and 13-18 have been rejected under 35 U.S. C. 103 as being unpatentable over Zimmer (Methods, 1999) in view of Vaish et al (NAR 1998) and Zhang et al (Human Gene Therapy 1999).

The action states that the term target tissue has been interpreted to include any tissue, and more specifically, the injection site. Applicants have amended claim 11, to insert the term “parenchymal cell”, clarify the term target tissue. Support for the amendment can be found in the specification on page 3 lines 12-13 and page 4 lines 8-25. The specification teaches that a parenchymal cell is a distinguishing cell of a gland or organ and often excludes cells that are common to many organs, specifically endothelial cells of blood vessels.

The Action further states that the tail vein is interpreted to be the efferent target tissue. The term “efferent target tissue” does not occur in the Applicants’ specification and is not a recognizable scientific term. The instant application teaches, on page 3 line 27 to page 4 line 2, that efferent blood vessels are defined as vessels in which blood flows away from the organ or tissue under normal physiologic conditions. Conversely, afferent blood vessels are defined as vessels in which blood flows to the organ or tissue under normal physiologic conditions. The tail vein in rodents is an afferent blood vessel of the liver because blood flows through the tail vein to the liver. Using the Applicants’ definition of afferent and efferent blood vessels, the tail vein would not be interpreted be those skilled in the art to be an efferent vessel of itself.

The Action states that the injection site represents a site of increased permeability. However, Zimmer does not teach injecting nanoparticles into the tail vein and delivering said particles to the tail vein. Therefore, Zimmer does not teach increasing permeability of blood vessels in the target tissue. Further, using the Examiner’s reasoning, the site of injection would represent increased permeability in a single vessel. Step b of Applicants’ claim 11 clearly states that permeability is increased in vessels in the target tissue.

To further differentiate Applicants' invention from the process taught by Zimmer, Applicants have further amended claim 11 to recite rapidly inserting the complex, in a large volume, into an efferent or afferent mammalian vessel...". Support for "rapidly inserting" can be found in the specification on page 3 lines 12-17 and page 7 line 19 to page 8 line 2. Support for "a in a large volume" can be found in the specification on page 3 lines 12-17 and page 7 lines 1-17.

The Examiner's objections and rejections are now believed to be overcome by this response to the Office Action. In view of Applicants' amendment and arguments, it is submitted that claims 11 and 13-18 should be allowable.

Respectfully submitted,

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I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as express mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this date: October 20, 2006.

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